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Title **Endoscopic Treatments for Gastroesophageal Reflux Disease: An Accelerated Systematic Review**

Agency **ASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures – Surgical**

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Aim

To assess the safety and efficacy of the following endoscopic anti-reflux treatments currently used for treating gastroesophageal reflux disease (GORD).

- Radiofrequency energy ablation (Stretta® Procedure).
- Endoluminal gastroplication (Bard® EndoCinch™, Wilson-Cook Endoscopic Suturing Device and NDO Plicator™).
- Injection/implantation techniques (Enteryx®, Gatekeeper™ Reflux Repair System and Plexiglas®).

Conclusions and results

Limited evidence suggested that in a select group of patients the *Stretta Procedure* improved symptoms and quality of life comparable to laparoscopic fundoplication (LF) and superior to sham treatment. Up to 10% of patients require further intervention after 2 years. The Stretta Procedure has fewer serious complications than LF, and rarely requires general anesthetic.

A single randomized controlled trial (RCT) comparing *EndoCinch* to sham treatment showed a significant placebo effect, but EndoCinch reduced esophageal exposure and medication use more than the sham procedure. Three small nonrandomized comparative studies suggested that EndoCinch provided the same, or slightly inferior, results compared to LF. Although EndoCinch was associated with a reintervention rate of up to 55% within 2 years, patients had fewer serious adverse events following EndoCinch than LF.

Two small case series studies on the *NDO Plicator* noted a positive effect on symptom and quality-of-life scores and medication use between 6 and 12 months after treatment.

A small RCT suggested that *Enteryx* has a substantial placebo effect. The manufacturer recalled Enteryx in 2005 after serious adverse events and 1 death were reported.

One case series reported improved symptoms, quality of life, and medication use 6 months after treatment with the *Gatekeeper Reflux Repair System*. Evidence for *Plexiglas* was sketchy. Both procedures were relatively safe.

Recommendations

The scope, applicability, efficacy, and cost effectiveness of endoscopic anti-reflux therapies in treating GORD are not established. These procedures may provide an alternative treatment for selected patients with mild to moderate GORD who are dependent on medication and are reluctant or unable to undergo surgery.

While the endoscopic anti-reflux procedures are relatively safe in a clinical trial setting, their use in routine practice should be closely monitored. Guidance from professional bodies on the minimum training requirements for performing these procedures would be helpful.

Methods

Search strategy: MEDLINE, EMBASE, CINAHL, PubMed, the Cochrane Library, Science Citation Index, the York Centre for Reviews and Dissemination, Clinicaltrials.gov, the National Research Register, relevant online journals, and the Internet were systematically searched without language restriction to May 2006.

Study selection: Systematic reviews, RCTs, and nonrandomized comparative studies with at least 10 patients in each study arm, and case series studies of at least 10 patients examining the efficacy and safety of the various endoscopic procedures were included for review.

Data collection and analysis: Data were extracted by one researcher and checked by a second using standardized data extraction tables developed *a priori*. The data were not suitable for statistical pooling, and a meta-analysis was not performed.

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